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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/428,122	10/27/99	MURDIN	A 19721-007-(P)

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EXAMINER

DEVI, S

ART UNIT

PAPER NUMBER

1645

7

DATE MAILED:

12/13/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/428,122

Applicant(s)  
Murdin et al.

Examiner  
S. Devi, Ph.D.

Group Art Unit  
1645



☒ Responsive to communication(s) filed on 10/03/00.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-37 ~~is/are~~ pending in the application.

Of the above, claim(s) 5-9, 15, 20-24, and 27-37 ~~is/are~~ withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-4, 10-14, 16-19, 25, and 26 ~~is/are~~ rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## **DETAILED ACTION**

### **Election**

1) Acknowledgment is made of Applicants' election filed 10/03/00 (paper no. 6), of invention I, claims 1-4, 10-14, 16-19, 25 and 26, in response to the restriction requirement mailed 07/12/00 (paper no. 3). Since Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

### **Status of Claims**

2) Claims 1-37 are pending.

~~Claims 5-9, 15, 20-24 and 27-37 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.~~

Claims 1-4, 10-14, 16-19, 25 and 26 have been elected via the election filed 07/21/00 and are under examination. An Action on the Merits for these claims is issued in the instant Office Action (paper no. 11).

### **Co-pending Applications**

3) At the time this Office Action was written, several copending applications related to this case, for example, SN 09/360,707, SN 09/361,440, ~~SN 09/428,122~~, SN 09/428,589, SN 08/713,236, SN 09/254,450, SN 09/360,434, SN 09/361,040, SN 09/361,443, SN 09/391,606, SN 09/427,501, SN 09/427,533, SN 09/430,723, SN 09/452,380, SN 09/471,194, SN 09/522,606, SN 09/523,647, SN 09/564,479, SN 09/609,243, SN 09/662,812, SN 09/662,814, SN 09/663,361 and SN 09/663,362 were not available to the Examiner of record for review. Applicants' assistance is requested in providing the Office with a copy of the pending claims from the co-pending applications relating to the presently claimed subject matter. Applicants are advised that any pending or allowed applications claiming the instantly claimed composition may serve as a grounds for a double patenting rejection in the next Office Action and that the next Office Action may be made final.

### **Sequence Listing**

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- 4) Acknowledgment is made of Applicants' raw sequence listing filed 02/07/00 (paper no. 4) which has been entered on 02/24/00 (paper no. 2).

**Domestic Priority**

- 5) The instant application claims priority to a provisional applications, SN 60/106,070, filed 10/29/98 and SN 60/122,066, filed 03/01/99.

**Information Disclosure Statement**

- 6) Acknowledgment is made of Applicants' Information Disclosure Statement filed 01/26/00 (paper no. 4). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 7).

**Drawings**

- 7) The drawings are objected to under 37 C.F.R. 1.84 because of the reasons set forth by the Draftsperson in the attached Form PTO 948 (paper no. 7). Correction is required.

**Oath / Declaration**

- 8) The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it was not executed in accordance with either 37 CFR 1.66 or 1.68. The oath/Declaration does not bear the signatures of the inventors.

**Specification - Informalities**

- 9) The specification is objected to for the following reason:
- (a) The drawing Figures 1 and 2 are labeled as Figure 1A to 1I and Figure 2A to 2H. However, these Figures are not referred to as Figure 1A to 1I and Figure 2A to 2H under the 'Brief Description of the Drawings' on page 8. Amendment to the specification is suggested to reflect this. It is suggested that Applicants examine the whole specification to make similar corrections, wherever reference to these Figures are made.
- (b) On page 16, line 17, the address of the American Type Culture Collection is incorrect. Effective 23 March 1998, ATCC has a new address: 10801 University Boulevard, Manassas, VA 20110-2209. Amendment to the specification is suggested to reflect this. It is

suggested that Applicants examine the whole specification to make similar correction to the address, wherever it appears.

(c) The use of the trademarks in the instant specification has been noted in this application. For example, see page 37, line 11 and page 51, line 5: "Tween 20"; and see page 60, line 3: "QIAquick™ PCR". Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### **35 U.S.C. 101 - Double Patenting Rejection**

10) A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4, 10-14, 16-19, 25 and 26 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 20, 21, 25-28, 32-35, 41 and 42 of co-pending application No. 09/376,770. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### **Rejection(s) under 35 U.S.C. § 112, First Paragraph**

11) Claims 1-4, 10-14, 16-19, 25 and 26 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;
- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

The instant specification is not enabled for a polynucleotide encoding a polypeptide having a sequence that is "at least 75% homologous" to SEQ ID NO: 2 and "functional fragments" thereof. Such a sequence with such a percent homology is not defined by the parametric values that were set when using the algorithm to compare sequences. Whether or not this homology encompasses a continuous stretch of identity or discontinuous stretches of homology is not understood. Without a clear and unambiguous description of how to perform the comparison, the scope of the claims cannot be envisaged. Without a specific disclosure of the parametric values used in the algorithm, the sequence identity between two sequences has no common meaning within the art and therefore, one of ordinary skill in the art cannot be sure of the sequences embraced by the claims and would not be able to make and use those polynucleotide or polypeptide sequence homologs as recited in the instant claims, without undue experimentation. One of ordinary skill in the art would not be able to make and use such homologous sequences, for example, as a vaccine or as a diagnostic reagent, because there is no disclosure as to what nucleotide or amino acid residues are embraced by the claims. The claims are viewed as not meeting the enablement provisions of 35 U.S.C § 112, first paragraph.

**Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

12) Claims 3, 4, 13, 17 and 19 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 3 and 4 lack antecedence for the recitation "The nucleotide of claim....". Claims 3 and 4 depend from claim 2, which recites either a "polynucleotide" or a "nucleotide sequence", but not a "nucleotide".

(b) Claim 13 lacks antecedent basis for the recitation: "The host cell of claim 10", because claim 10 is drawn to an expression cassette, but not to a "host cell".

(c) Claim 17 lacks antecedent basis for the recitation: "said host mammal". Claim 17 depends from claim 16, which does not recite any "host mammal".

(d) Claim 19 lacks antecedent basis for the recitation: "vaccine vector of claim 14", because claim 14 is drawn to a "host cell", but not to a "vaccine vector".

(e) Claim 14, which depends from claim 13, is also rejected under 35 U.S.C. § 112, second paragraph, because of the vagueness in the base claim(s) identified above in subparagraph (b).

#### **Rejection(s) under 35 U.S.C § 102**

13) Claims 1 and 25 are rejected under 35 U.S.C § 102(b) as being anticipated by Longbottom (GenEmbl Database Accession number U72499, 25 September 1996) (Longbottom, 1996).

Longbottom (GenEmbl Database Accession number U72499, 25 September 1996) discloses a sequence from *Chlamydia* which comprises several fragments having identity or stretches of identity to SEQ ID NO: 1 (see the enclosed search report). That such a polynucleotide or fragments (i.e., probes) thereof are capable of hybridizing with SEQ ID NO: 1 is inherent.

Claims 1 and 25 are anticipated by Longbottom (1996).

14) Claims 1, 4, 10-13, 16, 18, 19, 25 and 26 are rejected under 35 U.S.C § 102(b) as being anticipated by Longbottom *et al.* (*Infect. Immun.* 66: 1317-1324, April 1998) (Longbottom *et al.*, 1998).

Longbottom *et al.* (1998) teach chlamydial genes or sequences coding for highly immunogenic protein fragments comprising 8 or 9 amino acid residues (see attached search report; title and abstract). Polynucleotide probe reagents, DNA primers, expression vectors, host cells comprising the nucleotide sequence and sequences that hybridize with the disclosed genes are taught (see 'Materials and Methods' on page 1318, and page 1322).

The term "vaccine" is viewed as intended use of the product.

Claims 1, 4, 10-13, 16, 18, 19, 25 and 26 are anticipated by Longbottom *et al.* (1998).

### **Objection(s)**

15) Claims 19 and 25 are objected to for the following reasons:

(a) Claim 19 is incorrect in the recitation "a immunologically" (see line 1). The objection can be obviated by changing the recitation to --an immunologically--.

(b) Claim 25 is incorrect in the recitation "in biological material" (see lines 1 and 2) without a preceding article in between. The objection can be obviated by changing the recitation to --in a biological material--.

### **Remarks**

16) Claims 1-4, 10-14, 16-19, 25 and 26 stand rejected.

17) Claims 1-4, 10-14, 16-19, 25 and 26 of this application conflict with claims 1, 20, 21, 25-28, 32-35, 41 and 42 of application No. 09/376,770. 37 CFR 1.78(b) provides that when two or more applications filed by the same Applicants contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicants are required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week.

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD  
S. Devi  
Patent Examiner  
December 2000